

REMARKS

Prior to the present reply, claim 1-36 were pending. Due to a restriction requirement, claims 2-5, 7-12, 14-16, and 24-36 are withdrawn from consideration. Claims 1, 6, 13, and 17-23 are thus examined. These claims stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 6, and 17-22 are also rejected under 35 U.S.C. § 102(b) as being anticipated by Shimizu et al., J. Biol. Chem. 276:49003-49012, 2001 (“Shimizu”). Claims 1, 6, and 17-23 are further rejected under 35 U.S.C. § 103(a) as being obvious over Shimizu in view of PCT Publication WO 2000/023594 (“Gardella”). Claims 1, 6, and 17-23 are provisionally rejected for obviousness-type double-patenting over claims 1, 7, and 23-29 of U.S. Application No. 10/484,080 (“the ‘080 application”). Each of these rejections is addressed below.

Claim amendments

Claims 1-3, 5-9, 11-14, and 31 have been amended, claims 4, 10, 15, and 16 have been cancelled, and new claims 37-52 have been added. Claim 1 has been amended to recite that the peptide has a Trp, Bpa, or Arg at position 2, to recite “comprising” language, to clarify the claim language, and to delete reference to “N- or C- derivatives” and language regarding J domain selectivity. Claim 2 has been amended to clarify the claim language. Claims 3, 5-9, and 11-14 have been amended to recite “comprising” language, to clarify the claim language, and to delete reference to “N- or C- derivatives.” Claims 5 and 6 have also been amended to depend from new claim 49. Claim 31 has been amended to recite “reducing activity or production of PTH or PTHrP.” Support for this change is found, for example, in original claim 27. New claim 37 recites a peptide *consisting of* the peptide claim 1, a fragment thereof, or a pharmaceutically acceptable salt thereof. Support for this claim is found, for example, in original claim 1. Claim 38 likewise recites a peptide *consisting of* the peptide of claim 1 or a pharmaceutically acceptable salt thereof. Support for this claim is also found, for example, in original claim 1. New claims 39-48 recite the peptides of claims 3, 5-9, and 11-14, respectively.

Claim 49 recites the peptide of original claim 1, further requiring that position 1 of the peptide have a desamino form of an α -helix-stabilizing residue. Support for desamino forms of a helix stabilizing residues is found, for example, in original claim 2. Claim 50 recites the language of original claim 2, and claims 51 and 52 recite the language of claims 37 and 38. These amendments add no new matter.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 6, 13, and 17-23 are rejected as being indefinite for reciting “N- or C- derivatives thereof.” Without assenting to this rejection, Applicant has deleted this language from the claims. This rejection may accordingly be withdrawn.

Rejection under 35 U.S.C. § 102(b)

The Office rejects claims 1, 6, and 17-23 as being anticipated by Shimizu. In making this rejection, the Office asserts that Shimizu teaches a peptide having aminoisobutyric (Aib) substitutions at positions 1 and 3 of the rat PTH(1-14) sequence. Based on these teachings, the Office asserts that Shimizu teaches all limitations of claim 6, and thus anticipates this claim. Applicant respectfully disagrees.

Claim 6 recites a peptide having a desamino-Aib residue (i.e., an Aib residue that lacks the N-terminal amino group) at position 1 of the claimed sequence. Shimizu does not teach a peptide having a desamino-Aib amino acid, and thus does not teach all limitations of claim 6. Shimizu therefore cannot anticipate this claim.

Shimizu also fails to teach all limitations of amended independent claim 1 or claim 49, or their dependent claims.

Claim 1, as amended, recites a Trp, Bpa, or Arg amino acid at position 2 of the claimed sequence. Shimizu does not teach PTH peptides having Trp, Bpa, or Arg at position 2, and thus cannot anticipate independent claim 1 or any of dependent claims 17-23.

New independent claim 49 recites a peptide having a desamino amino acid at position 1 of the peptide sequence. As set forth above, Shimizu does not teach peptides containing desamino amino acids, and thus cannot anticipate independent claim 49 or its dependent claims.

Withdrawal of the § 102(b) rejection over Shimizu is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 6, and 17-23 also stand rejected under 35 U.S.C. § 103(a) as being obvious over Shimizu in view of Gardella. In making this rejection, the Office applies the teachings of Shimizu, as outlined above, to these claims. However, the Office notes that Shimizu does not teach ^{99m}Tc labeled peptides, as recited in claim 23. To remedy this deficiency, the Office cites Gardella as teaching PTH(1-14) peptides labeled with either ^{99m}Tc or ¹²⁵I. In view of these combined teachings, the Office finds claims 1, 6, and 17-23 to be obvious. Applicant respectfully traverses this rejection, as applied to the amended claims, on the basis that these references fail to teach all claim limitations.

Neither Shimizu nor Gardella teach or suggest a PTH peptide having a Trp, Bpa, or Arg at position 2, as recited in amended claim 1. Because these references fail to teach this claim limitation, either alone or in combination, these references cannot render claim 1 or dependent claims 6 or 17-23 as being obvious.

Further, new claim 49 and its dependent claims are likewise free from this rejection. Claim 49 recites peptides having a desamino amino acid at position 1. As neither Shimizu nor Gardella, alone or in combination, teach or suggest desamino peptide sequences, this combination of references cannot render claim 49 or its dependent claims as being obvious.

Withdrawal of the § 103(a) rejection is respectfully requested.

Provisional rejection for obviousness-type double patenting

Claims 1, 6, and 17-23 are provisionally rejected over claims 1, 7, and 23-29 of the ‘080 application for nonstatutory obviousness-type double patenting. In making this rejection, the Office asserts that the sequence

AibValAibGluLeuMetHisGlnHarGlyLysTrp recited in claim 7 of the ‘080 application meets the limitations of claim 6 of the present application. On this basis, the Office asserts that claims 1, 6, and 17-23 are obvious over the ‘080 claims. Applicant respectfully disagrees.

A finding of obviousness-type double patenting requires that at least one examined claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). M.P.E.P. § 804(II)(B)(1).

The claims of the ‘080 patent neither anticipate nor render obvious the claims of the present application and thus cannot render the present claims unpatentable on the grounds of obviousness-type double patenting.

Amended claim 1 and its dependent claims recite a PTH peptide having a Trp, Bpa, or Arg amino acid at position 2. The ‘080 claims do not teach this limitation, and thus cannot anticipate these claims. Further, the ‘080 claims provide no suggestion to make a PTH peptide having a Trp, Bpa, or Arg amino acid at position 2. On this basis, independent claim 1 and its dependent claims are free from the obviousness-type double patenting rejection set forth by the Office.

New claim 49 and its dependent claims recite a PTH peptide having, at position 1, a desamino form of an α -helix-stabilizing amino acid. The ‘080 claims do not teach this limitation and thus cannot anticipate claim 49 or its dependent claims. The ‘080 claims also do not suggest making a peptide having a desamino form of an α -helix-stabilizing amino acid. On this basis, independent claim 49 and its dependent claims are free from the obviousness-type double patenting rejection set forth by the Office.

Withdrawal of this rejection is respectfully requested.

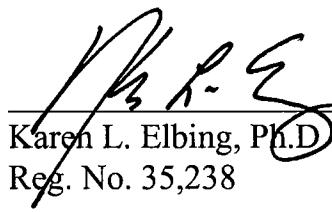
CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for two (2) months, to and including July 6, 2009. The Office is further authorized to charge Deposit Account No. 03-2095 in the amount of \$624.00 for 12 additional total claims in excess of the fees for 36 total claims paid for previously.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 06 July 2009


Karen L. Elbing, Ph.D.
Reg. No. 35,238

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045